An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Ambulatory Surgical Facilities and Services

Summary of Public Comments and Staff Recommendations

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Public Comment Deadline:
Friday, December 7, 2001

November 15, 2001

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Summary and Analysis of Public Comments and Staff Recommendation

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I. Introduction

The Maryland Health Care Commission's working paper, *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Ambulatory Surgical Facilities and Services*, was developed as one in a series of working papers examining major policy issues of the Certificate of Need (CON) process as required by House Bill 995 (1999). The paper was intended to provide a basis for public comment on a series of potential alternative regulatory strategies and related activities, presented as "options" in the working paper. Five CON program policy options were outlined (Options 1 through 5) and three options (Options 6 through 8) involving actions that could be taken independently within a range of CON program configurations were included in the paper:

Option 1: Maintain the existing scope of CON regulation

Option 2: Modify the existing scope of CON regulation with two changes

- Eliminate CON requirements for expansion of outpatient operating room capacity
- Eliminate potential for establishment of 2-operating room freestanding ambulatory surgical facilities through CON exemption

Option 3: Expand CON regulation to regulate establishment of any surgical facility or the addition of any operating rooms or procedure rooms by existing facilities

Option 4: Expand CON regulation to regulate establishment of any surgical facility providing services within a sterile operating room or the addition of any operating rooms by existing facilities

Option 5: Eliminate all CON regulation of surgical facilities and services

Option 6: Expand data collection from freestanding ambulatory surgical facilities

Option 7: Expand licensure of freestanding ambulatory surgical facilities to cover all such facilities

Option 8: Establish consistent definitions of surgical facilities and their components across licensure and CON regulation

The objective of this working paper was to provide information to the Commission on the desirability of implementing changes in the scope and/or process elements of CON regulation of ambulatory surgical facilities and services in Maryland. The working paper was released for public comment on September 19, 2001. Eleven (11) comments were received. Those comments are summarized in Part II of this report. A discussion of the comments, staff analysis and recommendations (which are interim at this time with respect to CON program policy), and an outline of research objectives for further analysis and iteration of appropriate policy is provided in Part III.

II. Summary of Public Comments

Comments on the Working Paper were received from: Adventist Healthcare, the Association of Maryland Hospitals & Health Systems, Carroll County General Hospital, Children's National Medical Center, Civista Surgery Center, HealthSouth Central Maryland Surgery Center (on behalf of HealthSouth Corporation), Johns Hopkins Health System, LifeBridge Health, Inc., the Maryland Ambulatory Surgical Association, the Health Services Cost Review Commission, and MedStar Health.

The comments are summarized in the following excerpts from the written comments.

ADVENTIST HEALTHCARE

- *… the public's interest is best served by some form of regulation over the supply and distribution of surgical facilities.*
- *It is of concern that the State of Maryland may be operating much less efficiently since the number of surgical cases per room is much lower than the other eight states in the comparison and has a much higher rate of freestanding ambulatory surgical facilities … perhaps, it would be worthwhile to modify the regulatory framework.*
- *… Option 8 would help clarify the situation related to ambulatory surgery.*

THE ASSOCIATION OF MARYLAND HOSPITALS & HEALTH SYSTEMS

- *… MHA feels that Option 1 … is the best approach at this time.*
- *… we support pursuing Option 7 … to enhance quality assurance and public safety.*
- *In order to resolve some of the definitional difficulties that have plagued these CON regulations over the past five years, we also recommend pursuing Option 8 to better define several critical terms and definitions.*

CARROLL COUNTY GENERAL HOSPITAL

- *… Maryland leads the nation, by a wide margin, in the number of Medicare-certified ambulatory surgery centers. … this situation is inefficient … the inefficiency inherent in single-specialty usage is why the General Assembly eliminated the single-specialty distinction in 1995.*

- *… supports Option No. 4. … this option will give the State a better tool as compared to the current CON policies to reduce the proliferation of inefficient ambulatory surgery capacity …*

- *… urges the Commission not to make any other changes to CON policies at the same time (such as relaxing consolidation and relocation rules). Rather, CCGH urges the Commission to move one step at a time, allowing itself the opportunity to analyze the impact of this measure on the health care system and the issues identified …*

- *… supports Option No. 6 so that the Commission may collect data on FASFs (including cost of surgical services, actual operating and procedure room times, and quality indicators).*

CHILDREN'S NATIONAL MEDICAL CENTER

- *… we would like to strongly support Policy Option 5 …*

- *If this policy option is not feasible, we would then like to support Policy Option 1*

- *In all, we support regulation that allows for competition and efficiency. By eliminating strict CON requirements for Ambulatory Surgery Centers, this can happen.*

CIVISTA SURGERY CENTER

- *… believe that the CON process should remain in use in the state of Maryland …Option 3 is what needs to be implemented. CON authorization for establishment of any type of surgical facility should be required … Need for operating rooms should drive this process.*

- *The physician's office calling themselves a surgery center does not come close to comparing to our (Civista Surgery Center) capabilities. Suggestions may be made to use different names for facilities based on the types and levels of care that they provide. The different tiers of facilities would be recognized and reimbursed appropriately as to the care they provide.*

- *Surgery Centers … should be providing the same or higher quality of care that inpatient facilities provide.*

- *… we must set specific definitions for what is a surgery center … we must compare apples to apples – not our 13,000 square foot facility (Civista Surgery Center) to a doctor's office that does not provide anesthesia, recovery or perform sterile procedures.*

- *… we must assure that all centers are regulated to ascertain that quality care is being provided.*

- *… reimbursement … must be increased. The current reimbursement is far from acceptable and contributes to the financial problems and constraints most facilities have …the Commission along with the Freestanding Ambulatory Surgery Centers most (sic) make reimbursement a priority so that quality of care is not jeopardized.*

HEALTHSOUTH CENTRAL MARYLAND SURGERY CENTER (ON BEHALF OF HEALTHSOUTH CORPORATION)

- *… strongly supports Option 1 …"if it's not broke, don't fix it."*

- *Continuity in policy for our regulated industry (ambulatory surgery) makes this (Option 1) desirable and this (Option 1) would eliminate the potential for any unanticipated consequences of policy change.*

- *… opposed to Options 2 though 5 …*

- *… takes issue with some of the Commission's stated concerns regarding higher number of ASFs in Maryland and higher numbers of cases in Maryland, both when compared to other States. This appears to be more of a function of the manner in which Maryland collects statistics on these subjects.*

- *… not supporting Options 3 and 4 is rooted in our belief that there should be flexibility for healthcare providers to establish one room facilities and procedure rooms that should not be restricted …*

- *… opposes Option 6 … without a better understanding of the need for such additional data …*

- *… supports the expansion of the scope of licensure, as described in Option 7, subject to MASA's request for a TAC to fine tune this expansion in light of the range of facilities that would become subject to licensure.*

- *… supports … suggestion in Option 8 that the terms "operating room" and "procedure room" should be defined; however, this support is conditioned upon the State's regulatory posture toward operating and procedure rooms not changing, since we support this only to facilitate data collection.*

JOHNS HOPKINS HEALTH SYSTEM

- *… supports a modified version of Option One.*

- *By continuing to regulate FASFs, there should be a smaller increase in the number of larger, multi-specialty FASFs.*

- *… supports the elimination of the requirement that hospitals must obtain a CON to add operating rooms used for outpatient surgery …*

- *Furthermore, merged asset systems should be able to relocate within their systems existing FASFs or other hospital-based outpatient operating or procedure rooms that it owns or controls without undergoing full CON review … The ability … to allocate existing ambulatory services within their systems allows hospitals to respond to market conditions without changing their overall surgical capacities, particulary with the proliferation of unregulated, single use, in-office physician surgery facilities … These regulatory changes would also facilitate the efficiency of operating room use in hospitals.*

- *In light of the Institute of Medicine's recent reports on patient safety and quality of care, Hopkins also supports Options 6 and 7.*

- *… (Option 6) would give MHCC the ability to develop a comprehensive system in which to evaluate all ambulatory surgery facilities and services …*

- *… both unlicensed surgery centers and single operating rooms located in physician offices should be held to certain basic standards, e.g., environmental, patient safety, human resources standards … imposition of full Medicare certification requirements is probably not necessary, but there should be some mechanism in place to ensure patient safety and enhance quality of care.*

LIFEBRIDGE HEALTH, INC.

- *LifeBridge supports the approach designated … as Option 2.*

- *The current system, under which hospitals must secure CON approval before building any ORs that will be used, even occasionally, for outpatient procedures, while no CON is required for the construction of ORs that will be used entirely for inpatient procedures, is, in our view, anomalous and unsupportable from a policy perspective.*

- *… it makes no sense to permit unlimited expansion of inpatient operating room capacity, while subjecting the development of less expensive and more efficient outpatient resources to full CON review.*

- *… we believe it remains appropriate for the creation of new facilities to be subject to CON review.*

- *… support eliminating the never-implemented mechanism for permitting single-OR, CON-exempt facilities to develop a second OR. The existing exemption … has resulted in the proliferation of these facilities … possibly at the expense of efficiency and quality oversight … the language in question could provide a back door through which even more outpatient procedures would be dispersed into smaller, unsupervised facilities, and believe it is wise to eliminate this opening.*

- *… supports the idea of extending State oversight to all sites at which invasive surgery is performed (Option 7) … the absence of any oversight of certain facilities is a glaring gap in our existing potential regulatory structure. While clearly not all facilities should be subject to the same standards, the implementation of a tiered level of licensure requirements for currently unregulated facilities will help ensure public safety and the provision of quality care.*

- *… supports the concept behind … Option 8 … ambiguity in the existing definition of "operating room" and "procedure room" has led to inconsistent practices. Precise definitions of these terms will help to ensure that the rules are applied consistently … the level of oversight is consistent with the actual services being performed.*

MARYLAND AMBULATORY SURGICAL ASSOCIATION

- *MASA is in full support of a more free market economy, with access to and equal competition within Maryland's health care system … moving forward, there should be a balance and separation between, on one hand, allowing the ambulatory surgical facility industry to continue to evolve and operate freely and, on the other hand, providing appropriate regulatory oversight of CON and quality assurance to promote the industry and protect patient safety.*

- *… MASA … understands the need for appropriate regulatory oversight by the state.*

- *It is the position of MASA that this regulatory system also continue a CON policy to provide the … Commission with appropriate regulatory tools and oversight of the ambulatory surgical facility industry … CON should remain a part of the regulatory policy of the state.*

- *… MASA is in support of Policy Option #1. We believe this option is in line with MASA's overall position on CON.*

- *Although Policy Options #2,3, and 4 address valid CON issues, MASA does not favor expanding CON regulation or making slight modifications which may have unintended consequences.*

- *… opposed to Option #5. Eliminating the CON process is … an option in which patient safety, quality assurance, and consumer protection may be adversely effected.*

- *… at this time, … opposed to Policy Option #6. Further data collection, unless the Commission can show that the information being collected will be useful, is expensive, time consuming and administratively burdensome to facilities … willing to work with the Commission and MHCC staff on appropriate data reporting if the need for expanded data collection can be shown and that the cost/benefit for the industry can be justified.*

- *… in support of Policy Option #7. … licensure should assist the Commission in addressing quality issues … help to identify where sub-par care is being rendered in unlicensed facilities. However, MASA … would suggest that the Commission do so (adopt Option 7) after a complete and thorough review … fully support the establishment of a Technical Advisory Committee which would be made up of industry representatives that could fully examine the issue of licensure and make recommendations …*

- *… very supportive of more clearly defining the terms "operating room" and "procedure room" (Option 8) … agrees … that regulations currently lack specificity …*

HEALTH SERVICES COST REVIEW COMMISSION

- *The Commission is generally supportive of promoting and encouraging competition in both hospital inpatient and outpatient settings. In theory, an increased number of health care services could increase the level of competition between programs and permit greater access for patients. Furthermore, greater competition should improve prices for Marylanders.*

- *The sentiment in the early 1990's shared by those parties involved in the Maryland health care market believed that increased ambulatory surgical facilities would promote competition and generally lower prices for Marylanders. Based on outpatient data submitted by Maryland hospitals, however, this dynamic has not occurred. In fact, a more disturbing trend has occurred in Maryland's regulated outpatient market where the Commission continues to see outpatient revenue and volume continuing to grow at nearly 18%.*

MEDSTAR HEALTH

- *… the CON program remains the State's most comprehensive regulatory tool for implementing health policies directed at:*

    - *Ensuring … development is consistent with state health goals …*
    - *Ensuring … services are financially and geographically accessible …*
    - *Ensuring patients can obtain optimal care*
    - *Ensuring that … providers are accountable*

- *… supports option 1 …*

- *The CON model of regulation ensures that there are adequate, quality ambulatory surgical services and that the services are geographically, financially and culturally accessible to patients.*

- *While opponents of the CON model of regulation say that CON restricts market entry and stifles competition, there is no evidence to support that theory in Maryland where freestanding surgical facilities are concerned.*

- *… we should remain cognizant of the impact on communities where competition between freestanding centers and hospitals might force a reduction of hospital services.*

- *To ensure that everyone has access to surgical services, some controls must remain in place regardless of whether the center is freestanding or hospital based.*

- *We urge the commission to maintain the current model of regulation with enhanced data collection and standardization of terms.*

- *Option 2 is not a viable option … as it would create an incentive for the development of inefficient surgical facilities.*

- *… Options 3 and 4 severely reduce opportunities for market entry and expansion of facilities.*

The two tables on the following page summarize explicit expressed support or opposition by the commenters to the options outlined in the working paper.

EXPLICIT SUPPORT (Full or qualified)

	True Status Quo	Practical Status Quo	Full Regulatory Coverage	Partial Regulatory Coverage	Deregulation	More Data	More Licensure	Define ORs and PRs
Commenter	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
Adventist								X
MHA	X						X	X
CCGH				X		X		
Children's					X			
Civista			X					
HealthSouth	X						X	X
JHHS	X					X	X	
LifeBridge		X					X	X
MASA	X						X	X
HSCRC								
MedStar	X					X		X
TOTAL	5	1	1	1	1	3	5	6

EXPLICIT OPPOSITION (Full or qualified)

	True Status Quo	Practical Status Quo	Full Regulatory Coverage	Partial Regulatory Coverage	Deregulation	More Data	More Licensure	Define ORs and PRs
Commenter	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8
Adventist								
MHA								
CCGH								
HealthSouth		X	X	X	X	X		
JHHS								
LifeBridge								
MASA		X	X	X	X	X		
HSCRC								
MedStar		X	X	X				
TOTAL	0	3	3	3	2	2	0	0

Part III. Discussion, Recommendations, and Proposed Research Agenda

Discussion of Comments on the Working Paper

Most of the commenters (9 of 11) indicated a preference for one of the program policy options (Option 1 – 5), which spoke to the scope of CON regulation of ambulatory surgical facilities. While each of the five options was supported by at least one commenter, Option 1, maintaining the current policies in the scope of CON regulation of ambulatory surgical facilities, was the most frequently identified preference, with the other four each receiving a single endorsement.

The support for Option 1 appears to be more firmly rooted in opposition or uncertainty concerning substantive changes in policy rather than any firm conviction that Maryland's existing CON regime for ambulatory surgery is optimal.

For example, the Association of Maryland Hospitals and Health Systems supports Option 1 without expressing any substantive basis for that support, other than stating that it "*is the best approach at this time*." HealthSouth Corporation supports its preference for Option 1 by stating (to paraphrase) that the current policy is not broken and therefore, does not need to be fixed and that "*continuity in policy*" is desirable.

Other comments offered by supporters of the status quo offer statements that appear to contradict or ignore major points made in the Working Paper. The Maryland Ambulatory Surgical Association (MASA) supports Option 1, and claims "*full support of a more free market economy, with access to and equal competition within Maryland's health care system.*" It then tempers this support by stating, "*Although MASA supports a free market system, it understands the need for appropriate regulatory oversight by the state. To that end, the Maryland CON program is designed to ensure that new health care services and facilities are developed only as needed, based on the publicly-developed measures of cost-effectiveness, quality of care, and geographic and financial access to care.*" However, the Working Paper clearly indicates that the

vast majority of currently licensed ambulatory surgical facilities in Maryland were developed without any determination of need or any evaluation of cost-effectiveness, quality, or access considerations and that the pattern of development in states that truly exemplify a system of free market entry, i.e., states without CON regulation of ambulatory surgery of any kind, appears to be quite different from that seen in Maryland.

Similarly, MedStar Health supports Option 1, stating that, "*The CON model of regulation ensures that there are adequate, quality ambulatory surgical services and that the services are geographically, financially and culturally accessible to patients*." As with the MASA comment, this statement appears to suggest that Maryland's current CON policies play a deliberate and active role in shaping the ambulatory surgical delivery system while the Working Paper demonstrates that, in contrast, those policies appear to have the effect of channeling the bulk of new outpatient surgical facilities development to the physician or other practitioner office setting, which is, for the most part, not subject to CON review or any consideration of geographic, financial, or cultural accessibility.

Finally, Johns Hopkins Health System supports Option 1, recommending that MHCC "*continue to regulate the establishment of freestanding ambulatory surgical facilities ('FASF') with two or more operating rooms and the expansion of such FASFs. The Working Paper indicates that Maryland has a higher concentration of Medicare-certified ambulatory surgery centers than any other state in the country. By continuing to regulate FASFs, there should be a smaller increase in the number of larger, multi-specialty FASFs*."

While staff agrees that continuing to regulate FASFs under CON in the same manner in Maryland will, in all likelihood, result in a smaller increase in larger multi-specialty FASFs (i.e., smaller than the increase in one operating room, office-based FASFs) , the comment juxtaposes two issues at the core of the central question posed by the Working Paper without directly addressing those issues. Maryland's CON policies establish real barriers to the establishment and expansion of larger FASFs, which are the types of FASFs which are most likely to offer multiple surgical specialties. They offer no effective barrier to the development of single operating room, office-based ambulatory surgery centers (ASC) or ASCs that limit themselves to the provision of "closed" invasive procedures in procedure rooms, rather than operating rooms. The result is that since 1994, the ASC with a single operating room or only procedure rooms, the 'office-based' capacity not subject to CON rules because it is not a health care facility in Maryland, has increased its position as the predominant ASC model in the state, accounting for 77% of total licensed ASCs in 2000 compared to 61% of total ASCs in Maryland in 1994. The Johns Hopkins Health System statement implies that there should be little or no concern with the unregulated 275% increase in these types of ASCs since 1994. It also does not address the issue of operational efficiency in surgical services delivery related to Maryland's current policies, and the decline in utilization of hospital and larger FASF operating room capacity which has occurred since 1994.

Support for the other four CON program policy options was, as noted, limited to a single commenter for each option. LifeBridge Health supported Option 2's elimination of the need for hospitals to secure a CON before adding additional outpatient (or mixed inpatient-outpatient) operating rooms because "*the current system … is … anomalous and unsupportable from a*

policy perspective" and that same Option's elimination of the opportunity for two operating room CON exemptions *as "a back door through which even more outpatient procedures could be dispersed into smaller, unsupervised facilities ….*" LifeBridge echoes the Working Paper's suggestion that current policy appears to be unbalanced in regulating most expansion of hospital operating suites that tend to be the largest and thus, potentially, the most efficient settings for surgery, while wholly exempting the large recent increase in single operating room facility establishment and additions of dedicated inpatient operating room capacity, a surgical category least likely to be used efficiently given the decline in inpatient surgical demand.

Civista Surgery Center recommends implementing Option 3, full CON regulation of the establishment of any FASF and the addition of any operating or procedure room by existing facilities, stating that the need for operating rooms should drive the CON process and citing financing inequities and potential quality problems associated with the unregulated increase in physician office surgical facilities allowed under current policies. Carroll County General Hospital (CCGH) supports Option 4, subjecting establishment of all FASFs with operating rooms and additions of operating rooms to CON regulation, citing the inefficiency of the single room physician office model and the proliferation of this type of FASF that has occurred in support of this choice. However, CCGH recommends this expansion of the scope of CON regulation as a single incremental change without the simultaneous implementation of other changes, such as policies that would promote consolidation of smaller ASCs, until sufficient time to evaluate the impact of the original regulatory initiative had elapsed. Finally, Children's National Medical Center supports elimination of surgical facilities development from CON regulation, Option 5, primarily because it may wish to expand the single operating room FASF it has established in Maryland and would like to avoid the regulatory burden that CON would place on such a project.

Support for the status quo is, essentially, opposition to further regulation or deregulation and can usually be viewed as a "safer" option, from a variety of perspectives, than attempting to perfect policy. Support for current policies creates a level of protection for the existing larger multi-specialty FASFs. Support for the status quo expressed by the hospital association and two hospital systems may reflect the view that the maintenance of current policy discourages development of the larger multi-specialty FASFs that tend to represent a more serious competitive challenge to hospitals. This view reflects the belief that less regulation of this industry is much more likely than more regulation. Tightening regulation is much more difficult to initiate and manage without creating unintended consequences. Support for greater regulation in the ambulatory surgical sector came from a hospital-affiliated FASF and a hospital. Likewise, support for loosening CON regulation of hospital additions of outpatient operating rooms and tightening CON exemption policy came from a hospital corporation. Support for deregulation came from a hospital which is not located in Maryland but operates a FASF located in Maryland.

Johns Hopkins Health System (JHHS) was the only commenter that offered a program policy option for consideration that was not outlined in the Working Paper and this actually modifies their stated support for the pure status quo position of Option 1 and may also help explain their opposition to more substantive policy changes. JHHS believes that "*merged asset systems should be able to relocate within their systems existing FASFs or other hospital-based outpatient operating or procedure rooms that it owns or controls without undergoing full CON*

review and approval. The ability of hospitals to allocate existing ambulatory services within their systems allows hospitals to respond to market conditions without changing their overall surgical capacities, particulary with the proliferation of unregulated, single use, in-office physician surgery facilities in Maryland. These regulatory changes would also facilitate the efficiency of operating room use in hospitals." In effect, JHHS seems to be arguing that Maryland's current policies need to be better balanced by allowing multi-hospital systems to reconfigure surgical assets within their system on an unregulated basis, as long as overall capacity is not increased.[1] If the key regulatory consideration is capacity control, it is unclear why independent hospitals should not also be allowed to move their operating rooms around the chess board, for example, by relocating existing operating rooms on their campus to a FASF, on an unregulated basis in order to better respond to changing market conditions and the proliferation of physician-office based ASCs. On the other hand, if, in fact, the key regulatory consideration is capacity control rather than location or configuration of operating and procedure rooms, this could be viewed as an argument for controlling the number of operating rooms in Maryland through CON regulation, something that current policies do not do. However, the JHHS suggestion would logically support a policy in which Maryland would regulate all market entry of new facilities and all room additions but, after such facilities and rooms go into operation, allow replacement and relocation to occur on an unregulated basis to maximize the ability of competing facilities to respond to changing market conditions. Like current policy, this would mean a Maryland CON program with only partial control of capital spending for surgical facilities but, unlike current policy, would give every person with control of a surgical facility the same ability to respond to market forces.

With respect to the non-program policy options, two of these options, expansion of FASF licensure beyond the current limits established by reimbursement (Option 7) and greater consistency in defining and regulating surgical room types across licensure and CON (Option 8) received support without any explicit opposition, although expanding the scope of licensure was only supported conceptually by some of the commenters, subject to further elaboration and study. Option 6, expanding data collection from FASFs, specifically to gather information on costs of FASF operations and quality, was explicitly supported by three commenters, all hospitals or hospital systems, and opposed, unless further justification could be provided, by two commenters, a non-hospital affiliated FASF and MASA. The response on these options suggests that MHCC should proceed with exploration of Options 6 and 7 in cooperation with the affected industry and that Option 8, which was supported by a larger number of commenters than any other option and opposed by none, should be implemented as soon as possible.

[1] With passage of HB 994, health planning statute allows a merged asset system some flexibility to move a health care facility within its system without a CON, subject to certain restrictions. (A physician office-based ASC is not considered a health care facility). If the relocation is within the facility's own primary service area, and within the capital expenditure threshold, a CON is not required. If the relocation is within the system's primary service area, a CON exemption decision by the Commission is required.

Staff Analysis and Recommendations

Overall Certificate of Need Program Policy

MHCC staff believes that the Working Paper has provided an important perspective on the course of ambulatory surgery since the last major policy review in 1994, and raised significant issues regarding the advisability of continuing current policies with respect to CON regulation of ambulatory surgical facilities and services. In the vernacular of one of the comments, we believe that there are strong indications that Maryland's policy in this area is "broken" and does need to be "fixed." However, staff also believes that the best approach for reforming that policy is not clear, based on the information gathered to date. The data brought together in the Working Paper strongly suggests, on a preliminary basis, two conclusions that do not support the maintenance of current policies:

1. Maryland's mix of regulatory policies is probably leading to a less efficient ambulatory surgical services delivery system than would be the case with either more regulation or less regulation than is currently exercised. This is based on the Working Paper's analysis that states with a more comprehensive scope of CON regulation of ambulatory surgical facilities and states without CON regulation of ambulatory surgical facilities have a smaller number of FASFs than Maryland that are, on average, larger than those in Maryland, more likely to offer multiple specialties than those in Maryland, and busier than those in Maryland.

2. Some of the problems identified in 1994 by the Maryland Health Resources Planning Commission (MHRPC) which gave rise to the current CON policy, and which the 1995 policy changes were intended to address, persist and have magnified since the new policy was implemented in 1995.

In 1994's *Ambulatory Surgery Services: Policy and Regulatory Issues*, the MHRPC staff found that "*There is more than sufficient surgical capacity in Maryland*" but, contrary to this finding, "*the numbers of single specialty ASCs in Maryland is growing very rapidly, which causes concern for systemwide costs and for potential fragmentation. The current regulatory system of exemptions has allowed rapid development of single specialty ambulatory surgery facilities … yet hospitals have responded to this new competitor and increasing capacity by increasing their own surgical capacity, which intensifies the problem.*" In 1994, Maryland had 74 single-specialty ASCs. In 2000, there were 185. In 1994, there were 470 total general and special purpose operating rooms located in Maryland's hospitals. In 2000, there are an estimated 517 such rooms.

The 1994 report went on to conclude that, "*In the absence of some regulatory response to this situation, incentives for new capacity development will continue, at least in the near term … If the current system of incentives continues, there is likely to be continued fragmentation and duplication. An evolving health care market will provide incentives that will lead to integration rather than fragmentation, but an adjustment to the regulatory framework is needed now to prevent unnecessary, duplicative and costly fragmentation.*" On the strength of these conclusions, the current CON policy limiting exemption of office-based FASF development

from CON regulation to single operating room facilities and eliminating the restriction of such exempted facilities from a select list of single specialties, i.e., the policy in place today, was put in place. As those changes were implemented in law in 1995, a policy regulating the addition by existing facilities of operating rooms that would be used to provide outpatient surgery was added to the CON law. As noted in the Working Paper, the growth in managed care and the HSCRC's emphasis on inpatient revenue provided strong financial incentives that propelled the growth in freestanding surgical capacity. Therefore, the use of these CON policies since 1995 has not led to a recognizably more integrated and less fragmented surgical services delivery system, and the overall decline in the average number of procedures per operating room strongly suggests that unnecessary duplication of operating and procedure room capacity continues to be a problem.

MHCC staff does not believe that the comments submitted in response to the working paper provide a basis for validating the current status quo in the CON regulation of ambulatory surgical facilities or elaborating a clear direction for policy reform.

Recommendation 1.
Staff recommends that, on an interim basis, no changes in ambulatory surgical facilities CON policy be proposed at this time. However, a research agenda should be developed and adopted that will clarify the likely impact of possible policy alternatives, both those that would place Maryland in a stronger regulatory posture and those that would relax CON regulation in this area, by the end of 2002. The ultimate objective of this research would be the validation or invalidation of the preliminary conclusion that current policies should be reformed and, if the former, the development of findings and conclusions which definitively indicate the appropriate direction of that policy reform.

Non- Certificate of Need Program Policy Options – Data, Licensure, Definitions

With respect to Option 6, staff believes that a necessary component of the research needed to clarify the best CON program policy options for Maryland is to better understand the cost consequences of Maryland's distinctive proliferation of physician and other practitioner office-based surgical facilities. Currently, MHCC does not collect any information on the actual cost of surgical services provided by FASFs. Only charge information is collected. There is no basis for comparing the actual cost of producing a unit of outpatient surgery in the hospital setting, the large, multi-specialty FASF setting, or the single OR physician office setting at the range of surgical volumes or for the various mix of surgical specialties which occur in these settings. Furthermore, MHCC is mandated to develop a system for comparative evaluation of quality of care outcomes and performance measurements for FASFs and the current scope of survey activity does not provide the types of information in this area needed for implementation of this performance reporting system.

Recommendation 2.
With respect to Option 6, staff recommends that revisions to the MHCC Ambulatory Surgical Facility Survey be initiated immediately for the 2001 survey cycle, with appropriate consultation and coordination with the affected providers, to address these data deficiencies. Additionally, the potential for a more focused

and detailed data collection effort for a stratified sample of FASFs should be explored with an appropriate work group of survey data responders and users as a component of the CON program policy research agenda noted above and as a means of better understanding the potential problems involved in including new required data elements in the general survey of all facilities.

Recommendation 3.
With respect to Option 7, MHCC staff recommends that, in cooperation with the Department of Health and Mental Hygiene's Office of Health Care Quality (OHCQ):

- Research should be undertaken to define the universe of facilities which currently exist in Maryland which serve as settings for invasive procedures but are not required to obtain licensure as a FASF because they do not seek reimbursement from payers as a freestanding ambulatory surgical facility and/or because they fall within one of the four excluded facility categories in current licensure regulations;

- Based on this research, a white paper outlining the costs and benefits of expanding the scope of FASF licensure to these unlicensed settings should be developed for review and comment by the public and interested parties, and;

- MHCC and OHCQ should consider the white paper and comments as a basis for recommendations on changes to the scope of FASF licensure to the Department of Health and Mental Hygiene.

Recommendation 4.
With respect to Option 8, staff recommends that a process be initiated immediately to develop a consensus among MHCC, OHCQ and the hospital and FASF industry on definitions of "operating room" and "procedure room" that are appropriate for use in facilities licensure and CON regulation and that these definitions be adopted in licensure and CON regulation as a basis for defining the licensed operating and procedure capacity of a hospital or FASF, accurately determining the FASF and hospital operating and procedure room inventory, and more effectively controlling the supply of operating rooms and, if necessary in the future, procedure rooms, through CON regulation.

Research Agenda

Recommendation 5.
In order to clarify the necessity for CON regulatory policy reform and the direction that reform determined to be needed should take (See Recommendation 1), MHCC staff recommends that the Commission expand on the work begun in the Working Paper. Staff proposes to develop a work plan that will identify

necessary resources and an appropriate timetable, and to solicit resources necessary to conduct research aimed at answering the following five interrelated questions:

- What is the impact of Maryland's current CON policies on the cost of producing ambulatory surgical services?

- What is the impact of current CON policies on the efficiency of operating and procedure room use in all surgical facility settings?

- What is the impact of current CON policies on the Medicare and Medicaid reimbursement paid to Maryland providers and on net revenue received from private payers for ambulatory surgical services?

- What is the impact of current CON policies on the population's use of ambulatory and inpatient surgical services?

- What is the impact of current CON policies on the quality of ambulatory surgical care outcomes?

The primary method proposed for investigation of these questions is a detailed comparative analysis of the ambulatory surgical services delivery system in a group of selected states, which will identify, to the extent possible, the following features and characteristics for each state:

- The regulatory system, if any, that has been used to control the supply and distribution of ambulatory surgical facilities and services. Some historical analysis will be required because regulatory mechanisms in some states have changed substantially in recent years, providing a potential for "before and after" impact analysis.

- The regulatory system, if any, that has been used to license ambulatory surgical facilities and services and the impact of such systems on supply, distribution, cost, and quality.

- The surgical services delivery system inventory of facilities, operating rooms, and procedure rooms, with an analysis of how these systems compare with that of Maryland when adjusted for differences in how various surgical settings are defined for purposes of licensure and reimbursement.

- Utilization of surgical facilities in a form that allows for comparative calculations of population use rates and utilization levels of system's capacity.

- Quantification of net revenue received for ambulatory surgery services from private payers and expenses for production of surgical services (available from some states) and Medicare and Medicaid reimbursement for outpatient surgery (professional fee

reimbursement for certified facilities and non-certified physician office-based surgery and facility fee reimbursement for certified facilities.)

- Analysis of other factors (insurance market profile, demographic and socio-economic characteristics) potentially influencing the surgical services developed within the state and their charges and costs.

The sources of information that will be used include a purchased database, the Freestanding Outpatient Surgery Centers/Chains Profiling Solution ©, developed by SMG Marketing Group, and secondary research by MHCC staff with CON, licensing, and health facility data resource organizations within each state. This latter research was initiated during development of the Working Paper.

The second area of research focus proposed is an in-depth analysis of the charge and cost structure of a sample of Maryland FASFs chosen to provide a representative cross section of this provider sector by specialty and size. This research will be aimed at identifying the relationship between costs and charges at an FASF and selected characteristics of the FASF, including range of specialties, types of specialties, volume of procedures, and competitiveness within the FASF's market service area. Findings from this research component will assist in answering the first and third questions listed above.

The third area of research focus proposed is on quality of care considerations, in particular, the relationship, if any, between volume and outcomes in ambulatory surgery. Maryland, because of its historic regulatory policies, has a high proportion of very low volume ambulatory surgical facilities. In 2000, over 43% of the total ambulatory surgical facilities in the state reported 260 or fewer total cases, an average of five or fewer surgical cases per week. Thirty-two facilities, over one out of every ten licensed FASF in the state, reported an average of less than one surgical case per week. This research will be aimed at identifying:

- Any literature examining the relationship between volume and outcomes in ambulatory surgery or profiling quality of care issues in the type of low volume and/or practitioner office-based surgical settings common to Maryland;

- Quality validation systems or data systems capturing FASF quality indicators used in other states that could be implemented in Maryland.

Findings from this research component will assist in answering the fifth question listed above and would also have a bearing on implementation of Recommendations No. 2 and 3 above.